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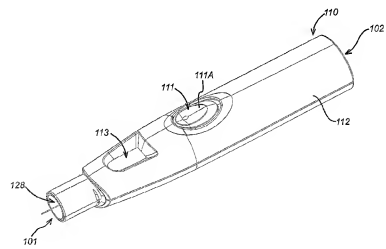
*[Continued on next page]*

(54) Title: INJECTION DEVICE




(57) Abstract: The present invention concerns an injection device (110) with a housing (112) adapted to receive a syringe (114) having a discharge nozzle (118), the housing having an indicator opening (113). There is a trigger (111) and a forward drive (132) arranged to act upon the syringe on actuation of the trigger to advance the syringe form a retracted position to an extended position thereby discharging the contents of the syringe through the discharge nozzle. A support member (122) is in contacting juxtaposition with the housing and a return drive (126) is supported by the support member and arranged to act upon the syringe after the contents of the syringe has been discharged so that the syringe can be withdrawn from the extended position to the retracted position. Advantageously, the support member is arranged in the housing so that the second drive does not obscure an inspection of the contents of the syringe through the indicator opening. Hence, it can be clearly determined whether the contents of the syringe have been expelled from the syringe.

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— *with international search report*

*For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

# INJECTION DEVICE

## FIELD OF INVENTION

The present invention relates to an injection device of the type that receives a syringe, extends it, discharges its contents and then retracts it automatically. Devices of this general description are shown in WO 95/35126 and EP-A-0 516 473 and tend to employ a drive spring and some form of release mechanism that releases the syringe from the influence of the drive spring once its contents are supposed to have been discharged, to allow it to be retracted by a return spring. The initial action of the drive spring is typically controlled by means of a trigger. Depression of the trigger causes the drive spring to become operative.

## BACKGROUND OF INVENTION

It is not uncommon for an injection device that has been previously used (i.e. a device which has been triggered and therefore has had the contents of its syringe discharged) to be mistaken for a device which has not been used. Although injection devices of this type may include an interlock to prevent further triggering of the device, market research has shown that it is beneficial for an injection device to provide some form of indication that the contents of the syringe has been completely discharged. This way, a user is able to determine immediately by visual inspection whether an injection device has been used. In particular, it has been shown that users of injection devices prefer a visual inspection of the actual syringe to see whether its contents has been discharged. With current injection devices, the return spring often surrounds the syringe thereby obstructing the view of the contents of the syringe. Furthermore, the sight of a return spring surrounding a syringe can be unappealing to a user of an injection device.

It is therefore an aim of the present invention to provide an injection device which gives a clear indication of whether the contents of a syringe has been discharged without the inner mechanical elements of the device being seen by a user. As ever, the simplest and cheapest way of achieving this is sought.

## SUMMARY OF THE INVENTION

In view of the foregoing, according to the present invention, there is provided a housing adapted to receive a syringe having a discharge nozzle, the housing having an indicator opening; a forward drive arranged to act upon the syringe on actuation to advance the syringe from a retracted position to an extended position thereby discharging the contents of the syringe through the discharge nozzle; a return drive arranged to act upon the syringe after the contents of the syringe have been discharged to withdraw the syringe from the extended position to the retracted position, characterised in that the return drive is arranged in the housing so that it does not obscure an inspection of the contents of the syringe through the indicator opening. Thus, there is a clear indication through the indicator opening of whether the contents of the syringe has been discharged. In addition, the inner mechanical elements of the device cannot be seen by a user. Furthermore, the indicator opening provides a large window which is not obscured and therefore allows the contents of the syringe to be checked for turbidity and the presence of particles indicating whether the contents of the syringe is safe to be injected.

In one embodiment of the present invention, the injection device comprises a support member which is in contacting juxtaposition with the housing and the return drive is supported by the support member.

Preferably, the support member is transparent and positioned between the indicator opening and syringe. This way, the internal contents of the syringe can be viewed. Before actuation, the liquid contents of the syringe will be viewable through the indicator opening. Transparent material that may be used for the support member is any rigid material which allows light to pass through (e.g. clear or opaque materials).

The support member may comprise a cylindrical insert dimensioned to contain the syringe; and a support surface for the return drive.

In one embodiment of the present invention, a first end of the return drive is in contacting juxtaposition with the support surface and a second end of the return drive is in contacting juxtaposition with the syringe. In a second embodiment of the present invention, the syringe carrier is dimensioned to contain the syringe, the cylindrical insert is dimensioned to contain the syringe carrier and a first end of the return drive is in contacting juxtaposition with the support surface and a second end of the second drive is in contacting juxtaposition with the syringe carrier.

Advantageously, the indicator opening is positioned so that a plunger of the syringe is viewable through the indicator opening when the contents of the syringe has been discharged. After discharge of the contents of the syringe, the plunger, which may be coloured with an easily identifiable colour, will be viewable through the indicator opening to indicate that the injection device has been used.

Preferably, the return drive is a helical spring surrounding at least part of the syringe. By surrounding the syringe with the helical spring, a single spring can be employed which is large enough to have a sufficient spring constant to return the syringe into itse retracted position.

Advantageously, the indicator opening comprises a transparent insert which allows inspection of the syringe without the syringe being damaged.

## BRIEF DESCRIPTION OF THE DRAWINGS

The invention will now be described by way of example with reference to the accompanying drawings, in which:

Fig. 1 shows in perspective an injection device of the type to which the present invention is applicable;

Fig. 2 shows in section the injection device of Fig. 1 before actuation; and

Fig. 3 shows in section the injection device of Figs. 1 and 2 after actuation.

## DETAILED DESCRIPTION OF THE DRAWINGS

Fig. 1 shows an injection device 110 having a housing 112 with a proximal end 101 and a distal end 102. The housing 112 has a trigger 111 which projects through the housing 112 and which can be actuated by pressing down on its upper surface 111a. There is a indicator opening 113 in the housing located adjacent the proximal end 101.

Fig. 2 shows the housing 112 containing a hypodermic syringe 114 of conventional type, including a syringe body 116 terminating at one end in a hypodermic needle 118 and at the other in a flange 120. The conventional plunger and bung that would normally be used to discharge the contents of the syringe 114 manually have been removed and replaced with a drive element 134 which includes a bung 134a. This drive element 134 constrains a drug 124 to be administered within the syringe body 116. Whilst the syringe illustrated is of hypodermic type, this need not necessarily be so. Transcutaneous or ballistic dermal and subcutaneous syringes may also be used with the injection device of the present invention. As illustrated, the housing includes a return drive which here takes the form of a compression return spring 126 that biases the syringe 114 from an extended position in which the needle 118 extends from an aperture 128 in the housing 112 to a retracted position in which the discharge nozzle 118 is contained within the housing 112.

The housing 112 includes a support member which, as shown in Fig. 2, takes the form of a cylindrical insert 122. The cylindrical insert 122 has, on its inner surface, a support surface 122a which connects with one end of the return spring 126. The other end of the return spring 126 acts on the syringe 114 via a syringe carrier 127. The support surface 122a is provided, as shown in Fig. 2, by a rim on the inner surface of the cylindrical insert 122. The support surface 122a is positioned beyond the indicator opening 113 away from the proximal end 101 of the housing 112. The return spring 126 connects with the support surface 122a on its end which is located away from the proximal end 101 of the housing 112 and its other end acts on the syringe carrier 127 beyond the support surface 122a from the proximal end 101 of the housing 112. This way, the return spring 126, which

surrounds the syringe 114 and syringe carrier 127, cannot be seen through the indicator opening 113 at any time before, during or after triggering of the injection device 110. The cylindrical insert 122 forms a window in the indicator opening 113 formed from transparent material so that the contents of the syringe 114 can be viewed through the indicator opening 113.

At the other end of the housing 112 is a forward drive, which here takes the form of a compression drive spring 130. Drive from the drive spring 130 is transmitted via a multi-component drive to the syringe 114 to advance it from its retracted position to its extended position and discharge its contents through the needle 118. The drive accomplishes this task by acting directly on the drug 124 and the syringe 114. Static friction between the drive element 134 and the syringe body 116 initially ensures that they advance together, until the return spring 126 bottoms out or the syringe body 116 meets some other obstruction (not shown) that retards its motion.

The multi-component drive between the drive spring 130 and the syringe 114 consists of three principal components. A drive sleeve 131 takes drive from the drive spring 130 and transmits it to a first drive element 132. This in turn transmits drive via a damping fluid to a second drive element, the drive element 134 already mentioned.

The first drive element 132 includes a hollow stem 140, the inner cavity of which forms a collection chamber 142 in communication with a vent 144 that extends from the collection chamber through the end of the stem 140. The second drive element 134 includes a blind bore 146 that is open at one end to receive the stem 140 and closed at the other. As can be seen, the bore 146 and the stem 140 defining a fluid reservoir 148, within which the damping fluid is contained.

The trigger 111, when operated, serves to decouple the drive sleeve 131 from the housing 112, allowing it to move relative to the housing 112 under the influence of the drive spring 130. The operation of the device is then as follows.

Initially, the drive spring 130 moves the drive sleeve 131, the drive sleeve 131 moves the first drive element 132 and the first drive element 132 moves the second drive element

134. The second drive element 134 moves and, by virtue of static friction and hydrostatic forces acting through the drug 124 to be administered, moves the syringe body 116 against the action of the return spring 126. The return spring 126 compresses and the hypodermic needle 118 emerges from the exit aperture 128 (shown in Fig. 3) of the housing 112. This continues until the return spring 126 bottoms out or the syringe body 116 meets some other obstruction (not shown) that retards its motion. Because the static friction between the second drive element 134 and the syringe body 116 and the hydrostatic forces acting through the drug 124 to be administered are not sufficient to resist the full drive force developed by the drive spring 130, at this point the second drive element 134 begins to move within the syringe body 116 and the drug 124 begins to be discharged. Dynamic friction between the second drive element 134 and the syringe body 116 and hydrostatic and hydrodynamic forces now acting through the drug 124 to be administered are, however, sufficient to retain the return spring 126 in its compressed state, so the hypodermic needle 118 remains extended.

Before the second drive element 134 reaches the end of its travel within the syringe body 116, so before the contents of the syringe have fully discharged, protrusions (not shown) on the first drive element 132 reach a constriction 137 within the housing 112. The constriction 137 moves the protrusions inwards so that the first drive element 136 is no longer coupled to the second drive element 134. Once this happens, the first drive element 136 no longer acts on the second drive element 134, allowing the first drive element 132 to move relative to the second drive element 134.

Because the damping fluid is contained within a reservoir 148 defined between the end of the first drive element 132 and the blind bore 146 in the second drive element 134, the volume of the reservoir 146 will tend to decrease as the first drive element 132 moves relative to the second drive element 134 when the former is acted upon by the drive spring 130. As the reservoir 148 collapses, damping fluid is forced through the vent 144 into the collection chamber 142. After release of the drive spring 130, some of the foree exerted by the drive spring 130 does work on the damping fluid, causing it to flow though the constriction formed by the vent 144; the remainder acts hydrostatically through the fluid and through friction between the first and second drive elements 132, 134, thence via the second drive element 134. Losses associated with the flow of the damping fluid do not

attenuate the force acting on the body of the syringe to a great extent. Thus, the return spring 126 remains compressed and the hypodermic needle remains extended.

After a time, the second drive element 134 completes its travel within the syringe body 116 and can go no further. At this point, the contents of the syringe 114 are completely discharged and the force exerted by the drive spring 130 acts to retain the second drive element 134 in its terminal position and to continue to cause the damping fluid to flow though the vent 144, allowing the first drive element 132 to continue its movement.

Before the reservoir 148 of fluid is exhausted, flexible latch arms 133 linking the drive sleeve 131 with the first drive element 132 are no longer forced to engage the drive sleeve 131 by protrusions 133a on the second drive element 134. Once this happens, the drive sleeve 131 acts no longer on the first drive element 132, allowing them to move relative to each other. At this point, of course, the syringe 114 is released, because the forces developed by the drive spring 130 are no longer being transmitted to the syringe 114, and the only force acting on the syringe will be the return force from the return spring 126. Thus, the syringe 114 is now returned to its retracted position and the injection cycle is complete.

All this takes place, of course, only once the cap 115 has been removed from the end of the housing 112. As can be seen from Fig. 2, the end of the syringe 114 is sealed with a boot 123.

Fig. 3 shows the injection device 110 after actuation of the injection cycle is complete. The second drive element 134 is located within the syringe body 116 so that it can be viewed through the indicator opening 113. The second drive element 134 is held within the syringe body 116, even though the drive sleeve 131 has been disengaged from the multi-component drive, by forked lugs 210 located on the second drive element 134. The forked lugs 210 have been forced through the constriction 137 so that they prevent rearward movement (i.e. movement in a direction from the proximal end 101 to the distal end 102) of the drive element 134. Thus, the drive element 134 is held in place within the syringe 116 so that it can be viewed through the indicator opening 113. The presence of the second drive element 134 in the syringe body 116 after discharge of the drug 124 acts

as an indicator to a user of the device 110 that the device 110 has been operated.

It will of course be understood that the present invention has been described above purely by way of example and that modifications of detail can be made within the scope of the invention.

CLAIMS

1. An injection device, comprising:

a housing adapted to receive a syringe having a discharge nozzle, the housing having an indicator opening;

a forward drive arranged to act upon the syringe on actuation to advance the syringe from a retracted position to an extended position thereby discharging the contents of the syringe through the discharge nozzle;

a return drive arranged to act upon the syringe after the contents of the syringe have been discharged to withdraw the syringe from the extended position to the retracted position,

**characterised in that** the return drive is arranged in the housing so that it does not obscure an inspection of the contents of the syringe through the indicator opening.

2. An injection device according to claim 1, further comprising a support member in contacting juxtaposition with the housing, wherein the return drive is supported by the support member.

3. An injection device according to claim 2, wherein the support member is transparent and positioned between the indicator opening and syringe.

4. An injection device according to any one of the preceding claims, wherein the support member comprises:

a cylindrical insert dimensioned to contain the syringe; and

a support surface for the return drive.

5. An injection device according to claim 4, wherein a first end of the return drive is in contacting juxtaposition with the support surface and a second end of the return drive is in contacting juxtaposition with the syringe.

6. An injection device according to claim 4, further comprising a syringe carrier dimensioned to contain the syringe, wherein the cylindrical insert is dimensioned to contain the syringe carrier and wherein a first end of the return drive is in contacting

juxtaposition with the support surface and a second end of the second drive is in contacting juxtaposition with the syringe carrier.

7. An injection device according to any one of the preceding claims, wherein the indicator opening is positioned so that a plunger of the syringe is viewable through the indicator opening when the contents of the syringe has been discharged.

8. An injection device according to any one of the preceding claims, wherein the return drive is a helical spring surrounding at least part of the syringe.

9. An injection device according to any one of the preceding claims, wherein the indicator opening comprises a transparent window.

10. An injection device, substantially as hereinbefore described with reference to the accompanying drawings.

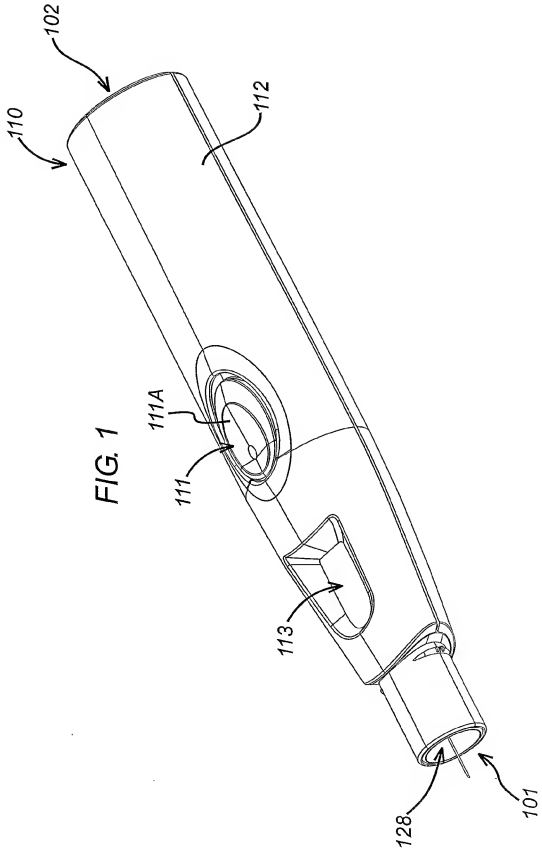


FIG. 1

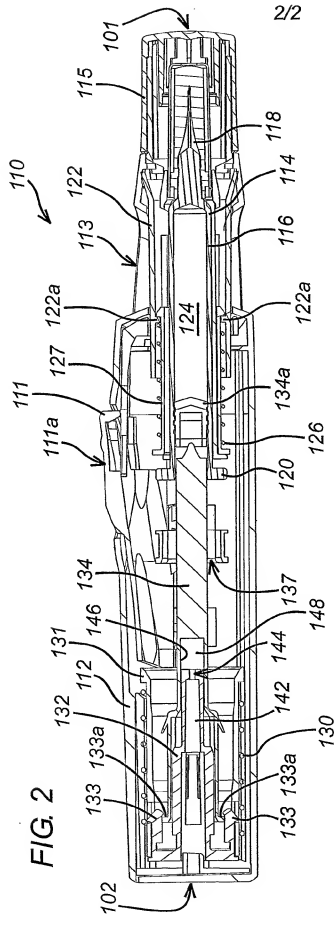
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FIG. 2

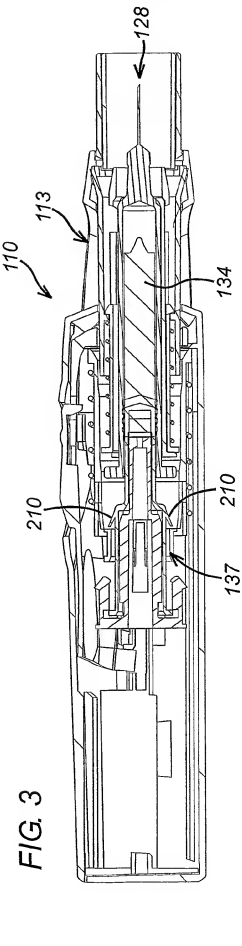
128
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FIG. 3

# INTERNATIONAL SEARCH REPORT

PCT/GB2005/002120

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M5/20 A61M5/32

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
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☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

'A' document defining the general state of the art which is not considered to be of particular relevance

'E' earlier document but published on or after the international filing date

'L' document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

'O' document referring to an oral disclosure, use, exhibition or other means

'P' document published prior to the international filing date but later than the priority date claimed

'T' later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

'X' document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

'Y' document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

'&' document member of the same patent family

| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 5 September 2005 | 09/09/2005 |

| Name and mailing address of the ISA | Authorized officer |
|---|---|
| European Patent Office, P.B. 5818 Patentlaan 2<br>NL - 2280 HV Rijswijk<br>Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,<br>Fax: (+31-70) 340-3016 | Ehrsam, F |

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Form PCT/ISA/210 (second sheet) (January 2004)

## INTERNATIONAL SEARCH REPORT

PCT/GB2005/002120

**Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)**

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☒ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
see FURTHER INFORMATION sheet PCT/ISA/210

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

**Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)**

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

**Remark on Protest**

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.2

Lack of clarity due to the reference to the drawings

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guideline C-VI, 8.5), should the problems which led to the Article 17(2) declaration be overcome.

# INTERNATIONAL SEARCH REPORT

Information on patent family members

PCT/GB2005/002120

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